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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,837	08/26/2003	Robert J. Sweeney	279.648US1	3849

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EXAMINER

FAULCON JR, LENWOOD

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/648,837	Applicant(s) SWEENEY ET AL.	
	Examiner Lenwood Faulcon, Jr.	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner takes the position that claim 36 is unclear as to the limitations that are being claimed by the Applicant, particularly the phrase "for at least one of the transmitting the acoustic and the receiving the acoustic energy."

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Siegel (U.S. Patent No. 5,062,841).

Siegel teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swellable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swellable member swells in response to an increase in blood glucose level (col. 3 lines 51-56). In regards to claims 1 and 2, Examiner takes the position that the hydrogel membrane as taught by Siegel has at least one physical

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property (swelling) that changes in response to a physiological condition (an increase in blood glucose level). Further, Examiner takes the position that change in size due to swelling, is inherently detectable by use of acoustic energy.

In regards to claims 3-6, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630) in view of Lew et al. (U.S. 2003/0100822), and further in view of Siegel (U.S. Patent No. 5,062,841) as applied above.

Altman et al. teaches of an implantable cardiac drug delivery system for delivery agents to be introduced within the myocardium of a subject (col. 9 lines 32-35), comprising a delivery patch or patches that may consist of a hydrogel (col. 12 lines 11-13), a catheter (col. 7 lines 56-61), and the use of an acoustic transmitter (col. 20 lines 39-43). The Altman et al. reference does specifically teach that hydrogels are commonly known in the art to be pH and/or ion sensitive, nor does the Altman et al.

reference teach that hydrogels are commonly known in the art to swell in response to a physiological condition.

Lew et al. teaches that hydrogels, including pH sensitive hydrogels, are well known in the art for being used as protective biocompatible coating for implantable devices, and are further defined as polymeric materials that swell in water and other fluids (paragraphs 7 and 9).

Siegel teaches of an implantable self-regulating mechanochemical insulin pump that has a biocompatible housing (col. 4 lines 29-33), which comprises an aqueous-swellable member (col. 7 lines 3-7) that includes a pH/ion sensitive hydrogel membrane. Siegel also teaches that the swellable member swells in response to an increase in blood glucose level (col. 3 lines 51-56).

In regards to claim 1, Examiner takes the position that hydrogel membrane that makes of the patch as taught by Altman et al. would be inherently capable of having at least one physical property change (swelling in size) in response to a physiological condition, such as an increase in blood glucose level since it is known that hydrogels have the characteristic, as taught by Siegel (col. 3 lines 51-56). In regards to claims 3-6 and 22-29, Examiner takes the position that the swelling of the membrane inherently changes the membrane's stiffness, acoustic reflection, acoustic transmission, and acoustic attenuation, by the very nature of its change in physical size. In the alternative, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Altman et al. to include hydrogels that are capable of swelling as taught by both Lew et al. and Siegel,

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since the hydrogels as taught by both Lew et al. and Siegel are well known in the art for being biocompatible membranes.

In regards to claims 8, 18 and 30, Examiner takes the position that implantable membrane could be of any shape, including spherical, and would be a matter of design choice. In regards to claims 18, Altman et al. teaches that of the use of multiple patches (70 and 75) that have membranes, which may comprise a hydrogel (col. 12 lines 11-13).

In regards to 12-15, Examiner takes the position that the Altman et al. reference inherently teaches of the use of a display, user interface and an external programmer, since the ultrasound transducer is being used in connection with ultrasound imaging (col. 20 lines 39-42). Examiner also takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system to include use of a computer network in connection with the user interface, since it is well known in the art to use a network for enhanced feedback and communication of detected results.

Allowable Subject Matter

7. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gough et al. (U.S. Patent No. 4,703,756), Zacouto (U.S. Patent

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No. 5,305,745), Slepian et al. (U.S. Patent No. 5,843,156), Herman et al. (U.S. Patent No. 6,350,463), Lew et al. (U.S. Patent No. 6,751,491).

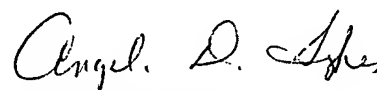
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


Lenwood Faulcon, Jr.


Angela Sykes

Supervisory Examiner

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